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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/276,868	03/26/1999	MICHAEL SIMONS	BIS-043	2716

7590 02/25/2004

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/276,868	SIMONS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed January 14, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 11-15 are pending.

Applicants' amendment filed January 14, 2004 is acknowledged, and applicant's response has been fully considered. Claims 11 and 15 have been amended, and claims 11-15 are under examination.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 of copending application 10/391,155 (US 2004/0009463). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11-15 in the instant application disclose a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated or protease-mediated degradation in-situ after introduction to

a viable cell, and each member being an oligopeptide having less than 26 amino acid residues, having N-terminal sequence of Arg-Arg-Arg, and being an analog of native PR-39 peptide. This is obvious in view of claims 10-13 of copending application which disclose a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated IκBα degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 39 amino acid residues, being at least partially homologous with the N-terminal sequence of native PR-39 peptide, and able to interact in-situ with IκBα in the cell. Since the claims of the instant application and those of the copending application are directed to a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated IκBα degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acid residues, being at least partially homologous with the N-terminal sequence of native PR-39 peptide, and being an analog of native PR-39 peptide. Thus, claims 11-15 in present application, and claims 10-13 of copending application are obvious variations of a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated IκBα degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acid residues, being at least partially homologous with the N-terminal sequence of native PR-39 peptide, and being an analog of native PR-39 peptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-15 are indefinite because of the use of the term "IκBα" or "HIF-1α". The term "IκBα" or "HIF-1α" renders the claim indefinite, it is unclear what the term "IκBα" or "HIF-1α" means. A fully spelled out word should be indicated in the first occurrence. Claims 11-15 are also indefinite as to "without substantially altering", it is not clear to what extent of the change other proteolytic degradation shows. Claims 12-14 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the term "a specific peptide" has been deleted, and each of the terms used in the pending claims is well understood, thus this ground of rejection should be withdrawn (pages 10-11). The argument is persuasive regarding the deletion of the term "s specific peptide, thus the rejection is withdrawn, however, the terms such as "IκBα", "HIF-1α" or "without substantially altering" are cited in the claim, it is not clear what the term means as indicated in the section above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Blecha *et al.* (WO 96-32129).

Blecha *et al.* teach PR-39 and the truncated analogs such as PR-14, PR-19 and PR-26, some of the peptides can inhibit leukocyte superoxide anion production and attract leukocytes, thus can be used as medicaments that fight infection by attracting leukocytes to a wound site to restrict tissue damage (page 3). The truncated analog PR-14 (RRRPRPPYLPRPRP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:4 (RRRPRPPYLPR, claim 13) or SEQ ID NO: 5 (RRRPRPPY, claim 14), and PR-19 (RRRPRPPYLPRPRPPPFFP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:3 (RRRPRPPYLPRPRPP, claim 12). These truncated analogs of PR-39 such as PR-14 and PR-19, which have the same structural features as the claimed PR-39 oligopeptides, e.g., having less than 26 amino acid residues, having N-terminal Arg-Arg-Arg, and having identical amino acid sequence to the N-terminal region of native PR-39 peptide, would be expected to have the characteristics, traits or properties of the claimed peptides cited in the claim (claims 11 and 15) since they have the same amino acid sequences as the claimed sequence of SEQ ID NO: 3, 4 or 5.

In response, applicants indicate that the rejection made by Examiner is based solely and exclusively upon the legal doctrine of "inherency", and the basis of "inherency" requires a factual determination of whether those aspects of the claimed subject matter that are not directly taught in the single prior art reference-the missing descriptive information were nonetheless known in the field of the inventions by practitioners ordinarily skilled in that technical area; the Examiner must demonstrate the prior art reference, directly or indirectly, discloses and provides

all the requisite elements and particular limitations defined by the claim, as well as identifies the resulting capabilities, properties and traits recited by the claim language with substantial certainty; and Blecha *et al.* teach the synthesized anti-microbial peptides are analogs or truncated peptides of PR-39 peptide such as PR-14, PR-19 and PR-26 peptides, however, only PR-26 analog was found to have anti-microbial activity, the PR-14 and PR-19 analogs failed to show any anti-microbial activity, thus, Blecha *et al.* only teach the limited utility of PR-26 peptide as anti-microbial agent, the reference does not teach to those skill in the art the requisite elements and limitations of applicants' claimed invention, directly or indirectly (pages 11-33 of the response). The response has been fully considered, however, the argument is not found persuasive because Blecha *et al.* teach the same truncated PR-39 peptides (e.g., PR-14 and PR-19) as the oligopeptides cited in claims 12, 13 or 14 (e.g., peptides comprising SEQ ID NO:3, 4 or 5), and PR-14 and PR-19, which have the same structural features as the claimed PR-39 oligopeptides, e.g., having less than 26 amino acid residues, having N-terminal Arg-Arg-Arg, and having identical amino acid sequence to the N-terminal region of native PR-39 peptide, would be expected to have the same properties and traits as the claimed PR-39 oligopeptides. Thus, the properties of the claimed PR-39 oligopeptides such as inhibiting proteasome-mediated degradation, being pharmacologically active, or interacting in-situ with the $\alpha 7$ subunit of proteasomes in the cytoplasm of the cell would be expected for the peptides of PR-14 and PR-19, even though the cited properties are not indicated in the reference. Use "a peptide consists of SEQ ID NO: 3, 4 or 5" would avoid the rejection.

Conclusion

4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

February 19, 2004